

UNITED STATES DISTRICT COURT

JUL 12 2007

SOUTHERN

DISTRICT OF

TEXAS Michael N. Milby, Clerk

UNITED STATES OF AMERICA
V.

CRIMINAL COMPLAINT

KEVIN XU

Case Number: H-07-624M

(Name and Address of Defendant)

I, the undersigned complainant state that the following is true and correct to the best of my knowledge and belief. On or about April 10, 2007 in Harris County, in the Southern District of Texas defendant(s) did,

(Track Statutory Language of Offense)

knowingly and intentionally conspire with subjects, known and unknown, to knowingly and intentionally traffick in counterfeit pharmaceutical drugs namely Viagra and Cialis without the authorization of the registered holders of the trademarks.

in violation of Title 18 & 21 United States Code, Section(s) 371, 2320(a) & 331(i).

I further state that I am a(n) ICE Special Agent and that this complaint is based on the following facts:

See Attached Affidavit

Continued on the attached sheet and made a part of this complaint: ☐ Yes ☐ No

Signature of Complainant

S/A Robert Sherman

Printed Name of Complainant

Sworn to before me and signed in my presence,

7/12/2007

Date

at

Houston, Texas

City and State

Stephen W. Smith, Magistrate Judge

Name and Title of Judicial Officer

Signature of Judicial Officer

AFFIDAVIT IN SUPPORT OF CRIMINAL COMPLAINT

I Robert M. Sherman, being duly sworn, depose and state:

1. I am a citizen of the United States and a resident of the State of Texas.
2. I am a Criminal Investigator with U.S. Immigration and Customs Enforcement (ICE) and it's predecessor the U.S. Customs Service since 1991. From 1981 to 1991 affiant was an officer and Sergeant with the Houston Police Department. Based upon my training and experience I am knowledgeable about criminal laws concerning counterfeiting of pharmaceutical drugs in violation of Title 21, United States Code, Section 331(I) , conspiracy and trafficking in counterfeit goods, in violation of Title 18, United States Code, Sections 371 and 2320(a).
3. This affidavit in support of a criminal complaint for the arrest of KEVIN XU for violations of the Food Drug and Cosmetic Act (FDCA) , conspiracy and criminal trademark offenses by trafficking in counterfeit pharmaceutical drugs.

INTRODUCTION

4. The United States Food and Drug Administration (FDA) is the agency of the United States charged with the responsibility of protecting the health and safety of the American public by ensuring, among other things, that drugs sold for administration to humans bear labeling containing true and accurate

information. The FDA's responsibilities include regulating the labeling and distributing of prescription drugs shipped or received in interstate commerce.

5. United States Immigration Customs Enforcement (ICE) is an agency of the United States charged with the responsibility of investigating the smuggling of contraband into the United States to include counterfeit merchandise.
6. Under the Food, Drug and Cosmetic Act, the definition of a "drug" includes articles which (1) are intended for use in the diagnoses, cure, mitigation, treatment or prevention of disease in man, and (2) are intended to affect the structure or function of the body of man. Due to the toxicity and other potential harmful effect, certain drugs are not considered safe for use except for use under the supervision of a practitioner licensed by law to administer such drugs. These drugs are known as prescription drugs.
7. Viagra was a prescription drug product that had been approved by the FDA for distribution within the United States.
8. Pfizer Pharmaceuticals (Pfizer) had the exclusive right to manufacture Viagra for distribution within the United States.
9. The name "Viagra" was a trademark owned by Pfizer and is registered in the principal registry in the United States Patent and Trademark Office.
10. Zyprexa was a prescription drug product that had been approved by the FDA for distribution within the United States.
11. Eli Lilly Corporation (Eli Lilly) had the exclusive right to manufacture Zyprexa for distribution within the United States.

12. The name "Zyprexa" was a trademark owned by Eli Lilly and is registered in the principal registry in the United States Patent and Trademark Office.
13. Tamiflu was a prescription drug product that had been approved by the FDA for distribution within the United States.
14. Roche Corporation (Roche) had the exclusive right to manufacture Tamiflu for distribution within the United States.
15. The name "Tamiflu" was a trademark owned by Roche and is registered in the principal registry in the United States Patent and Trademark Office.
16. Plavix, was a prescription drug product that had been approved by the FDA for distribution within the United States.
17. Sinofi Aventis had the exclusive right to manufacture Plavix for distribution within the United States.
18. The name "Plavix" was a trademark owned by Sinofi Aventis and is registered in the principal registry in the United States Patent and Trademark Office.
19. Casodex was a prescription drug product that had been approved by the FDA for distribution within the United States.
20. Astra Zeneca had the exclusive right to manufacture Casodex for distribution within the United States.
21. The name "Casodex" was a trademark owned by Eli Lilly and is registered in the principal registry in the United States Patent and Trademark Office.
22. The Food Drug and Cosmetic Act also regulates the importation, delivery, distribution and receipt of prescription drugs in interstate commerce. Under

the Act, a prescription drug is deemed misbranded if its labeling is false or misleading in any particular manner. A prescription drug is also deemed to be counterfeit if it bears a trademark without the authorization of the registrant of the trademark.

FACTS AND CIRCUMSTANCES

23. Your affiant and other officers of U.S. Immigration and Customs Enforcement (ICE) and the Food and Drug Administration Office of Criminal Investigation (FDA/OCI) have been involved in the investigation of ORIENT PACIFIC INTERNATIONAL, a company based in the People's Republic of China (PRC). ORIENT PACIFIC INTERNATIONAL and a person known as KEVIN XU are suspected of smuggling counterfeit prescription pharmaceutical drugs into the United States. Investigators working for several major pharmaceutical companies provided information that XU was involved in the distribution of counterfeit pharmaceutical products. During a meeting with investigators, XU stated he had a partnership with a German, an American and another Chinese in the manufacture of counterfeit pharmaceuticals. On March 6, 2007, affiant, working in an undercover capacity, met an individual who identified himself as Kevin XU in Bangkok Thailand. XU was subsequently identified as Lu XU. Affiant represented to XU that affiant wanted to purchase large volumes of prescription pharmaceuticals for introduction into the legitimate United States wholesale

distribution chain. XU and affiant discussed XU's pharmaceutical manufacturing and distribution venture. XU provided an extensive list of brand trademark pharmaceutical drugs he offered for sale. XU admitted to providing three shipments containing pharmaceutical drugs that had previously been ordered by an Eli Lilly company investigator and delivered to an undercover ICE mail drop in the United States. Those shipments consisted of Tamiflu, Zyprexa and Plavix that laboratory analysis deemed counterfeit. XU maintained he could manufacture tablets and packaging in 10,000 tablet production runs. XU provided detailed suggestions for transshipment and smuggling techniques to evade United States Customs detection. The list included, but was not limited to Tamiflu, a registered trademark of Roche prescribed for influenza, Zyprexa, a registered trademark of Eli Lilly prescribed for bi-polar disorder, Casodex, a registered trademark of Astra Zeneca prescribed for prostate cancer and Plavix, a registered trademark of Sinofi Aventis for the treatment of blood clots.

24. Affiant subsequently commenced e-mail negotiations with XU using an e-mail address he provided for the purpose of future purchases of pharmaceuticals. On March 22, 2007, XU provided via e-mail wiring instructions for an HSBC bank account in Beijing to wire payment.
25. On April 2, 2007, affiant, via XU's e-mail address ordered 100 strips of Tamiflu, 50 boxes of Zyprexa, 20 boxes of Casodex and 10 boxes of Plavix for a total cost of \$5720 in United States currency. Affiant wired payment to a HSBC bank account designated by XU. Later that evening affiant spoke to

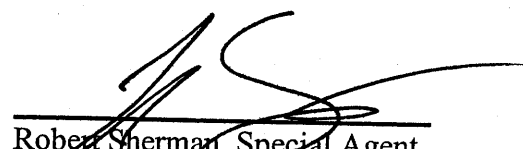
XU on his cellular telephone and XU agreed to fill the order. On April 9, 2007, XU e-mailed affiant two waybill tracking numbers for the order and a third waybill tracking number for another order previously made by an Eli Lilly investigator.

26. On or about April 13, 2007 affiant received several shipments from XU. The first shipment contained 183, 10-count Tamiflu strips and was delivered to the designated mail drop in Houston, Texas. The tablets were submitted to the FDA laboratory for analysis and were deemed counterfeit.
27. The second shipment contained 80, 7-count strips and boxes of Zyprexa and 100, 10-count strips of Tamiflu. They were also delivered to the designated mail drop in Houston, Texas. The tablets were submitted to the FDA laboratory for analysis and were deemed counterfeit.
28. The third shipment contained 50, 7-count boxes of Zyprexa, 10, 28-count boxes of Plavix and 20, 30-count boxes of Casodex. The tablets were submitted to the FDA laboratory for analysis and were deemed counterfeit.
29. On April 22, 2007 affiant received another shipment containing 160, 7-count strips of Zyprexa, 80, 20-count boxes of Zyprexa, 40 empty Zyprexa boxes and 130, 28-count boxes of Plavix. This shipment was an order previously made by an Eli Lilly investigator. The tablets were submitted to the FDA laboratory for analysis and were deemed counterfeit.
30. On May 31, 2007 affiant e-mailed XU an order for 150 strips of Tamiflu, 20 boxes of Plavix and 20 boxes of Aricept. Affiant wired \$5,220 in United States currency to XU's designated HSBC account. On June 1, 2007, XU e-

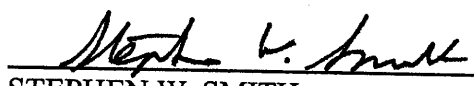
mailed affiant that he had received the funds and agreed to fill the order. Also on or about June 1, 2007, a Pfizer investigator met XU in China to discuss the purchase of counterfeit pharmaceuticals. In the course of that meeting, XU stated he anticipated traveling to the United States in July or August of 2007 for his chemical business. The statement regarding United States travel is similar to the statement XU made to affiant during the March 6, 2007 Bangkok meeting.

31. On June 12, 2007 affiant received 20, 28-count boxes of Aricept, 20, 28-count boxes of Plavix and 150, 10-count strips of Tamiflu at the designated mail drop in Houston, Texas. The tablets were submitted to the FDA laboratory for analysis. The Pfizer laboratory analyzed the Aricept and deemed it counterfeit. The analysis by the FDA laboratory also deemed the tablets counterfeit.
32. Subsequent to the March 6, 2007 meeting in Bangkok, affiant has conducted e-mail and telephonic negotiations with XU to expand the United States distribution of XU's counterfeit pharmaceuticals. In response to product recalls of counterfeit pharmaceuticals in the United Kingdom bearing lot numbers identical to pharmaceuticals provided by XU, he has agreed to produce packaging with lot numbers and expiration dates provided by affiant. XU agreed to meet in Houston, Texas on or about July 24, 2007 to consummate an agreement for widespread distribution of his counterfeit

products in the United States.


Robert Sherman, Special Agent
Department of Homeland Security
Immigration Customs Enforcement

SWORN TO AND SUBSCRIBED BEFORE ME ON THE 12, DAY OF
JULY, 2007, AND I FIND PROBABLE CAUSE.


STEPHEN W. SMITH
UNITED STATES MAGISTRATE JUDGE